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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,926

04/30/2008

Francesca Levi-Schaffer

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09/22/2011

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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

09/22/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,926	<b>Applicant(s)</b> LEVI-SCHAFFER ET AL.	
	<b>Examiner</b> NORA ROONEY	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 42-45, 47, 48 and 50-52 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 42-45, 47-48, 50-52 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/12/2011</u> . | 6) <input type="checkbox"/> Other: ____.  |

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### DETAILED ACTION

1. Applicant's amendment filed on 06/30/2011 is acknowledged.
2. Claims 42-45, 47-48 and 50-52 are pending and under consideration as they read on bi-specific antibodies and in vivo methods of treating allergic disease.
3. Applicant's IDS document filed on 09/12/2011 is acknowledged. The reference has been considered, but it has been crossed off because it is not a publication with a publication date.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 42-45, 47-48 and 50-52 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a bi-specific antibody comprising: (i) a, first target recognition component which specifically binds to the inhibitory receptor IRp60; and (ii) a second target recognition component which specifically binds to IgE, cKIT, CCR3, IL-5R or FcRI and a method of treating allergies comprising administering a bi-specific antibody comprising: (i) a, first target recognition component which specifically binds to the inhibitory receptor IRp60; and (ii) a second target recognition component which specifically binds to IgE, cKIT or CCR3, the specification does not provide reasonable enablement for: a bi-specific antibody comprising: (i) a first target recognition component which specifically binds to the inhibitory receptor IRp60; and (ii) **a second target recognition component which specifically**

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**binds to a marker specific for a mast cell, an eosinophil and/or a basophil, said marker being selected from the group consisting of IgE, cKIT, CCR3, IL-5R and FceR1** of claim 42; and a method of treating an allergy, the method comprising administering to a subject in need thereof a therapeutically effective amount of a bi-specific antibody comprising: (i) a first target recognition component which specifically binds to the inhibitory receptor IRp60; and (ii) **a second target recognition component which specifically binds to a marker specific for a mast cell, an eosinophil and/or a basophil, said marker being selected from the group consisting of IgE, cKIT and CCR3**; thereby treating the allergy of claim 52 and as applied to claims 43-45, 47-48 and 50-51.

The markers IgE, cKIT, CCR3 and IL-5R are not specific for a mast cell, an eosinophil or a basophil. The term “specific for” implies that the marker identifies the cell type and none of these markers identify basophils, mast cells or eosinophils by their expression. In addition, c-KIT (CD117) recognizes the cell surface receptor for Stem Cell Factor (SCF). The interaction of the mouse c-kit receptor and stem cell factor promotes proliferation and differentiation of hematopoietic progenitor cells and participates in erythropoiesis in both the bone marrow and spleen in addition to being expressed by mast cells. (In particular, see PTO-892; Reference U). CCR3 mediates selective recruitment of eosinophils into tissue and is expressed on cells involved in allergic inflammation, such as basophils, mast cells, airway epithelial cells and TH2 T-lymphocytes (In particular, see PTO-892; Reference V). Therefore, the specification is not enabled for the recited markers being “specific for” basophils, eosinophils and/or mast cells.

In addition, IgE is an antibody isotype and is not expressed by eosinophils, basophils or mast cells at all. These cells express the receptor for IgE, but not IgE itself.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 12, 2011

/Nora M Rooney/

Primary Examiner, Art Unit 1644